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Effect of Oral Mekobalamin on Peripheral Neuropathy in Leprosy Patients: A Pre–Post Clinical Study

Putu Evindya Vipascitadewi Nandanaya Bharata[1], Luh Made Mas Rusyati[1], Luh Putu Ratih Vibriyanti Karna[1], Nyoman Suryawati[1], IGN Darmaputra[1], Ni Made Dwi Puspawati[1]

[1]Department of Dermatology and Venereology, Faculty of Medicine, Udayana University. Jl. Diponegoro, Denpasar 80114, Bali, Indonesia.

Corresponding Author : Putu Evindya Vipascitadewi Nandanaya Bharata

Email: nandanaya.bharata@unud.ac.id

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ABSTRACT

Leprosy remains a significant public health problem in Indonesia, and peripheral neuropathy is a major cause of disability in affected patients. This study aimed to evaluate the effectiveness of oral mekobalamin in reducing neuropathic pain and improving peripheral sensory function in leprosy-related neuropathy. A pre-experimental one-group pre–post clinical study was conducted from March to May 2023 involving 31 adult leprosy patients. Participants received oral mekobalamin 500 micrograms every eight hours for 90 days. Neuropathic pain was assessed using the Douleur Neuropathique-4 and Leeds Assessment of Neuropathic Symptoms and Signs questionnaires. Sensory function was evaluated using the Semmes–Weinstein monofilament test. Statistical analysis was performed using paired t-tests. The mean Douleur Neuropathique-4 score decreased from 6.39 ± 1.38 to 5.13 ± 1.12 ($p<0.001$), and the mean Leeds Assessment of Neuropathic Symptoms and Signs score decreased from 16.45 ± 2.79 to 14.11 ± 2.86 ($p<0.001$). Significant improvement in tactile sensation was observed in selected peripheral nerves. Oral mekobalamin administered for three months significantly reduced neuropathic pain and improved peripheral sensory function, suggesting its potential role as adjunct therapy in leprosy neuropathy.

Keywords : leprosy; peripheral neuropathy; mekobalamin; neuropathic pain; sensory function

INTRODUCTION

Leprosy remains a major public-health problem in many endemic regions, particularly in Indonesia, where the prevalence ranks among the highest worldwide. In 2019, more than 200,000 new cases were reported globally, with over 14,000 cases originating from Indonesia alone (WHO, 2020). Mycobacterium leprae has a predilection for Schwann cells, leading to inflammation, demyelination, and axonal degeneration that cause neuropathic pain, sensory loss, and long-term disability (Calderone et al., 2024; Pilaka et al., 2024). Neuropathy is one of the most debilitating complications of leprosy, frequently persisting after multidrug therapy and contributing significantly to stigma and poor quality of life (Huang et al., 2024; Raicher et al., 2018).

Current therapeutic strategies for leprosy-related neuropathy rely mainly on corticosteroids to suppress acute neuritis and prevent nerve function impairment (Bhushan et al., 2018). Although effective in reducing inflammation, prolonged corticosteroid therapy carries substantial adverse effects and does not reverse established nerve damage (WHO, 2021). This therapeutic limitation underscores the urgent need for safe adjunctive approaches that can promote nerve regeneration and provide sustainable relief from neuropathic symptoms. Neurotropic vitamins, particularly B-complex formulations, have been considered for this purpose and are frequently prescribed in clinical practice (Calderón‑Ospina & Nava‑Mesa, 2020; Mehta et al., 2024).

Among neurotropic vitamins, mekobalamin (methylcobalamin), the active coenzyme form of vitamin B12, has demonstrated superior neurological activity. Experimental studies show that mekobalamin promotes axonal transport, enhances myelin basic protein synthesis, and stabilizes mitochondrial function, thereby facilitating remyelination and nerve recovery (Calderón-Ospina et al., 2023; Okada et al., 2010; Sawangjit et al., 2020). Clinical investigations in diabetic and chemotherapy-induced neuropathy further support its role in improving sensory function and reducing neuropathic pain (T. Purwata et al., 2015; Shibuya et al., 2014). However, most previous studies have focused on metabolic or chemotherapy-induced neuropathies, while evidence in infectious neuropathy, particularly leprosy-related nerve damage, remains very limited. Existing reports primarily describe symptomatic management without structured evaluation using validated neuropathic pain scales or objective sensory testing (Sil et al., 2018; Tiago et al., 2021).

This gap in the literature provides the rationale for evaluating mekobalamin specifically in patients with leprosy-related peripheral neuropathy. Unlike previous studies that examined methylcobalamin in diabetic or non-infectious neuropathies, this study focuses on neuropathy caused by Mycobacterium leprae and evaluates clinical outcomes using both validated neuropathic pain instruments and objective monofilament sensory testing. The present study was conducted to assess the effectiveness of three-month oral mekobalamin therapy in reducing neuropathic pain and improving peripheral sensory function. We hypothesised that treatment would significantly decrease Douleur Neuropathique-4 (DN4) and Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) scores, as well as enhance tactile sensation on the Semmes–Weinstein monofilament test, thereby providing new clinical evidence for its potential role as an adjunct to standard leprosy management in endemic settings.

METHODS

Study design

This study used a pre-experimental one-group pre-post clinical design conducted from March to May 2023 at the Dermatology and Venereology Clinic, Prof. Dr. I.G.N.G. Ngoerah Hospital, Denpasar, Indonesia.

Population and sample

The population consisted of adult leprosy patients with clinical signs of peripheral neuropathy. Inclusion criteria were age ≥18 years and willingness to participate. Exclusion criteria included diabetes mellitus, pregnancy, renal or hepatic failure, corticosteroid use, and hypersensitivity to vitamin B12. Thirty-one patients were recruited consecutively.

Data collection

Participants received oral mekobalamin 500 mcg every eight hours for 90 days. Neuropathic pain was measured using DN4 and LANSS questionnaires. Sensory function was evaluated using the Semmes–Weinstein monofilament test at standardized nerve sites. Demographic data were obtained from medical records.

Data analysis

Data were analyzed using SPSS version 26. Continuous variables were expressed as mean ± standard deviation. Paired t-tests were used to compare pre- and post-treatment scores. Statistical significance was set at $p<0.05$ with a 95% confidence interval.

Ethical statement

This study received ethical approval from the Research Ethics Committee of the Faculty of Medicine, Udayana University and Prof. Dr. I.G.N.G Ngoerah Hospital (No. 781/UN14.2.2.VII.14/LT/2023). Written informed consent was obtained from all participants.

RESULTS AND DISCUSSION

Thirty-two patients initially met the inclusion criteria, but one participant with uncontrolled diabetes mellitus died of hypoglycemia before receiving mekobalamin, leaving thirty-one patients who completed the study. The mean age of participants was 38.77 ± 8.67 years, with 21 males (67.5 %) and 10 females (32.3 %). The most common occupation was self-employed (41.9 %), and the highest education level achieved by most participants was senior high school (41.9 %). Baseline demographic and clinical characteristics, including occupational and educational distributions, are presented in Table 1.

Table 1. Demographic and Baseline Characteristics of Participants

Characteristic	n (%) or Mean ± SD
Age (years)	38.77 ± 8.67
Sex	Male 21 (67.5); Female 10 (32.3)
Occupation	Self-employed 13 (41.9); Retired 2 (6.5); Civil servant 4 (12.9); Builder 2 (6.5); Unemployed 6 (19.4); Teacher 2 (6.5); Farmer 1 (3.2); Laborer 1 (3.2)
Education	Senior high school 13 (41.9); Junior high school 7 (22.6); Diploma 1 4 (12.9); Bachelor 4 (12.9); Elementary school 3 (9.7)
DN4 score	Before 6.39 ± 1.38; After 5.13 ± 1.12
LANSS score	Before 16.45 ± 2.79; After 14.11 ± 2.86

Neuropathic Pain Outcomes

After three months of oral mekobalamin combined with vitamins B1 and B6, there was a significant reduction in neuropathic pain. The mean Douleur Neuropathique-4 (DN4) score decreased from 6.39 ± 1.38 to 5.13 ± 1.12, and the mean Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) score decreased from 16.45 ± 2.79 to 14.11 ± 2.86. Paired t-test analysis showed a mean DN4 difference of 1.26 ± 0.86 (95 % CI 0.94–1.57; $p < 0.001$) and a mean LANSS difference of 2.29 ± 1.13 (95 % CI 1.88–2.71; $p < 0.001$). These results are summarized in Table 2.

Table 2. Changes in DN4 and LANSS Scores Before and After Treatment

Variable	Mean Difference ± SD	95 % CI (Lower–Upper)	p-value
DN4	1.26 ± 0.86	0.94 – 1.57	<0.001*
LANSS	2.29 ± 1.13	1.88 – 2.71	<0.001*

*Paired t-test, $p < 0.05$ considered significant.

Peripheral Sensory Function

Improvement in tactile perception was observed in several peripheral nerves after mekobalamin therapy. Significant changes were recorded in the left ulnar, right radial, left radial, and left median nerves. Other sites including the right ulnar, right median, and bilateral tibialis and peroneus nerves did not show significant changes. The distribution of mean monofilament scores and color responses before and after treatment is detailed in Table 3. These findings indicate that oral mekobalamin given with vitamins B1 and B6 for three months leads to significant improvement in neuropathic pain and selective enhancement of peripheral nerve sensory function, particularly in the left ulnar, right and left radial, and left median nerves.

Table 3. Monofilament Test Results by Nerve Site

Nerve & Side	Mean ± SD Before	Mean ± SD After	Mean Difference ± SD	95 % CI (Lower–Upper)	p-value
Ulnar Right	3.74 ± 0.45	3.84 ± 0.37	–0.10 ± 0.30	–0.21 – 0.01	0.083
Ulnar Left	3.45 ± 0.58	3.68 ± 0.54	–0.13 ± 0.34	–0.25 – (–0.00)	0.043*
Radial Right	3.35 ± 1.02	3.48 ± 0.51	–0.26 ± 0.45	–0.42 – (–0.10)	0.003*
Radial Left	3.33 ± 0.71	3.87 ± 0.34	–0.32 ± 0.70	–0.58 – (–0.07)	0.016*
Median Right	3.06 ± 0.51	3.32 ± 0.87	–0.10 ± 0.54	–0.29 – 0.10	0.325
Median Left	3.29 ± 0.46	3.45 ± 0.50	–0.23 ± 0.43	–0.38 – (–0.07)	0.006*
Tibialis Right	2.68 ± 0.87	3.00 ± 0.96	0.00 ± 0.37	–0.13 – 0.13	1.000
Tibialis Left	2.71 ± 1.01	2.84 ± 0.93	–0.16 ± 0.45	–0.33 – 0.01	0.057
Peroneus Right	2.71 ± 0.82	2.81 ± 0.87	–0.13 ± 0.56	–0.34 – 0.08	0.211
Peroneus Left	2.71 ± 0.78	2.90 ± 0.76	–0.19 ± 0.54	–0.39 – 0.01	0.056

*Paired t-test, $p < 0.05$ considered significant.

The present study demonstrates that three months of oral mekobalamin combined with vitamins B1 and B6 significantly reduced neuropathic pain and improved peripheral sensory function in patients with leprosy-related neuropathy. The observed decreases in DN4 and LANSS scores and the improvements in Semmes–Weinstein monofilament responses confirm the hypothesis that mekobalamin exerts both analgesic and neuroregenerative effects, directly addressing mechanisms of oxidative stress, nitric-oxide production, and Schwann-cell injury described in previous studies (Braune et al., 2023; Calderone et al., 2024; Frade et al., 2022; Pilaka et al., 2024). By supplying the active coenzyme form of vitamin B12, mekobalamin supports methylation of myelin basic protein, enhances axonal transport, and stabilizes mitochondrial function, thereby promoting remyelination and peripheral nerve recovery (Okada et al., 2010).

The demographic profile of participants aligns with global and regional epidemiological patterns of leprosy. Most patients were in the productive age range, which is consistent with findings that leprosy commonly affects adults between 30 and 40 years of age (Wijaya et al., 2021). Male predominance in this study mirrors previous findings suggesting higher exposure risk among men due to mobility and social activity (Steinmann et al., 2017). The occupational and educational distribution also corresponds with reports from endemic areas indicating that socioeconomic factors, low literacy, and poverty contribute to disease transmission and progression (Sarode et al., 2020; A. F. Teixeira & Viana, 2016; C. S. S. Teixeira et al., 2019).

Significant reductions in DN4 and LANSS scores after treatment reflect the clinical effectiveness of mekobalamin. The magnitude of improvement is comparable to previous studies describing baseline DN4 scores around 6–7 in leprosy neuropathy (Ebenezer & Scollard, 2021; Toh et al., 2018). Improvement in neuropathic pain following vitamin B12 supplementation has also been reported, supporting the analgesic role of methylcobalamin (Sil et al., 2018). Furthermore, the improvement in monofilament responses suggests recovery of large-fiber sensory function rather than mere symptomatic relief. Similar improvements in monofilament scores and sensory thresholds have been demonstrated in diabetic neuropathy after high-dose methylcobalamin therapy (Frade et al., 2025; T. E. Purwata et al., 2021; Rodrigues Júnior et al., 2025). Previous studies have also documented extensive sensory impairment in untreated leprosy, reinforcing the clinical relevance of sensory improvement observed in this study (Frade et al., 2021; Villarroel et al., 2007).

Mechanistic explanations for these findings are well supported by experimental and clinical evidence. Mekobalamin is the neurologically active form of vitamin B12 required for transmethylation and methionine synthase activity, facilitating myelin synthesis and axonal regeneration (Scalabrino et al., 2003). Experimental models demonstrate that mekobalamin enhances protein synthesis and promotes remyelination of damaged nerves (Okada et al., 2010). Clinical trials in diabetic and hereditary neuropathies have further shown that high-dose mekobalamin improves sensory function and reduces neuropathic pain (Dave et al., 2024; T. E. Purwata et al., 2021; Shibuya et al., 2014). These converging findings strengthen the interpretation that the clinical benefits observed in this study are attributable to mekobalamin's neurotrophic and analgesic mechanisms rather than spontaneous remission.

The implications of these findings are both theoretical and practical. Theoretically, they support the concept that oxidative stress and demyelination are central mechanisms in leprosy neuropathy and can be mitigated by agents that enhance methylation and axonal transport (Calderón-Ospina & Nava-Mesa, 2020). Clinically, mekobalamin may serve as a valuable adjunct to multidrug therapy and corticosteroids, offering a safer long-term strategy for managing chronic neuropathic pain and potentially reducing prolonged corticosteroid exposure, which is associated with substantial adverse effects (WHO, 2021).

Despite these promising results, several limitations should be acknowledged. The absence of a control group restricts causal inference, and the single-center design with a relatively small sample size may limit generalisability. Additionally, the three-month follow-up period may not fully capture long-term nerve regeneration. Future studies should include randomized controlled trials with larger populations, extended follow-up durations, and assessment of inflammatory biomarkers such as IL-6, IL-1β, and TNF to further clarify the sustained clinical impact of mekobalamin therapy.

Overall, this study demonstrates that three months of oral mekobalamin administration effectively reduces neuropathic pain and improves peripheral sensory function in patients with leprosy-related neuropathy. The significant reductions in DN4 and LANSS scores, along with improved monofilament responses, provide evidence that mekobalamin supports peripheral nerve repair in accordance with the pathophysiology of Mycobacterium leprae-induced nerve injury. These findings contribute to the growing body of evidence supporting targeted vitamin therapy as a safe adjunct in chronic neuropathic conditions and warrant further validation through larger controlled trials.

CONCLUSION

This study demonstrates that three months of oral mekobalamin administration significantly reduced neuropathic pain scores and improved peripheral sensory function in patients with leprosy-related neuropathy. The significant decreases in DN4 and LANSS scores, along with selective improvement in monofilament responses, suggest that mekobalamin may support nerve repair and functional recovery. Although the absence of a control group limits causal interpretation, these findings indicate that mekobalamin can be considered a potential adjunctive therapy in the management of leprosy-associated peripheral neuropathy. Further randomized controlled trials with larger sample sizes are required to confirm its long-term effectiveness and clinical impact.

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